

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION

No. 1:19-md-2875-RBK  
Hon. Robert Kugler

*This relates to: All Actions*

**Plaintiffs' Memorandum of Law in  
Opposition to Defendants' Motion to  
Exclude the Expert Testimony of  
Rena Conti, Ph.D.**

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO  
DEFENDANTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF  
RENA CONTI, PH.D.**

On the Brief:

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## **I. INTRODUCTION**

In her Declaration, Dr. Rena Conti, a qualified healthcare economist and current Associate Professor of Markets, Public Policy and Law in the Questrom School of Business at Boston University, reliably applies a generally accepted methodology to establish the fact of economic damage. After establishing fact of damage, she then reliably applies her methodology to calculate aggregate damages on a class-wide basis. The same principal methodology Dr. Conti applies here was found to be reliable by another court in this Circuit in a litigation just like this one that involved worthless, adulterated drugs.

Defendants, over the course of two separate briefs spanning forty pages (D.E. 2037 & 2040), vainly try to shoehorn their overarching arguments against class certification into the Rule 702 rubric of qualifications, reliability, and fit. But Defendants' quibbles with Dr. Conti's conclusions or inputs do not implicate the admissibility of her opinions. If these veiled class certification arguments have any bearing on Dr. Conti's report at all, they go to weight and credibility, and not admissibility.

*First*, Dr. Conti is a preeminently credentialed healthcare economist, who has served as an advisor to the U.S. Food and Drug Administration ("FDA") on issues related to generic drug pricing and supplies. Manufacturer and Retailer Defendants do not even challenge her qualifications. Wholesalers' fleeting

qualifications argument, in which they call Dr. Conti's economic damages calculations into question because she never worked for a wholesaler or signed a drug purchase contract, is spurious. By comparison, Defendants' economists, Ms. Punam Keller and Dr. Lauren Stiroh, are equally rooted in academia, and neither has ever worked for any corporate entity in the drug supply chain. It defies logic that a long academic record would *de facto* disqualify someone as an expert. Dr. Conti is sufficiently qualified under Rule 702.

**Second**, Defendants' reliability arguments as to Dr. Conti's report are singularly focused on her conclusion (*viz.*, whether adulterated drugs have any economic value or not), and not her methodology. This represents an upheaval of the *Daubert* analysis, is unmoored from the law of the jurisdiction, and is completely without merit. Further, at this class certification stage, the question is not whether the factfinder will credit Dr. Conti's "no economic value" approach over Defendants' competing "some value" approach to damages, but whether Dr. Conti's analysis is a common, reliable method for estimating class damages. It is.

**Third**, Defendants' contention that Dr. Conti's opinions do not fit the facts of this case (because they will not assist the trier of fact) is likewise without merit. Indeed, Dr. Conti's methodology is the only economic methodology offered by either party which recognizes the stringent and tightly regulated landscape of the prescription drug pharmaceutical market, and tracks Plaintiffs' theories of liability.

*Fourth*, in terms of the facts and data underlying Dr. Conti's opinions, she unquestionably relies on actual, real-world data to calculate economic harm at the point of sale. Defendants' hair splitting over which underlying facts or data should be incorporated in her model is an argument that goes to weight, not admissibility. Data points that Defendants themselves lambast Dr. Conti for failing to include are sets of data (e.g., rebates) that the Defendants refused to produce in the litigation. This alone precludes exclusion. It is also immaterial, because Dr. Conti's model is flexible enough to incorporate additional data if and when it becomes available, or to be molded based on which state-law claims or Defendants proceed to trial first after class certification

*Finally*, as to unjust enrichment, the blame for the Wholesaler and Retail Pharmacy Defendants ("Downstream Defendants") criticisms of Dr. Conti's opinion rests squarely with them. The profits and cost data these Downstream Defendants assail Dr. Conti for not incorporating was data they themselves refused to produce at each turn.

For these reasons, discussed more fully below, Defendants' *Daubert* motions (D.E. 2037 and 2040) should be denied.

## **II. APPLICABLE LEGAL STANDARD**

"Under the Federal Rules of Evidence, a trial judge acts as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also

reliable.’” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted). Rule 702, the rule that governs expert testimony, has a “liberal policy of admissibility.” *Id.* In essence, the expert testimony must meet the following requirements: “(1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert’s testimony must assist the trier of fact.” *Id.* at 244.

#### **A. Qualifications**

The qualification requirement of Rule 702 is “liberally construed” and satisfied if an expert “possesses specialized expertise.” *Geiss v. Target Corp.*, 2013 WL 4675377, at \*4 (D.N.J. 2013) (citing *Pineda*, 520 F.3d at 244).

#### **B. Reliability**

The second Rule 702 requirement (also known as reliability) is taken to “mean[] that the expert’s opinion must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation.’” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (citation omitted). While such “good grounds” for an expert’s opinion are required, “[t]he grounds for the expert’s opinion merely have to be good, they do not have to be perfect.” *Id.* at 744. Good grounds may exist even if the court believes there “are better grounds for some alternative conclusion” or that “a scientist’s methodology has some flaws

such that if they had been corrected, the scientist would have reached a different result.” *Id.*

Moreover, proponents of expert testimony do not have to “demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.” *In re DVI, Inc. Sec. Litig.*, , 2014 WL 4634301, at \*5 (E.D. Pa. Sep. 16, 2014) (internal quotation marks omitted) (emphasis original); *see also In re Paoli*, 35 F.3d at 744 (“evidentiary requirement of reliability is lower than the merits standard of correctness”). Scientific study is not the only basis for an expert’s reliability – it may also be founded upon experience. As the Supreme Court later added in *Kumho Tire*, the objective of *Daubert* is to “make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The *Daubert* test “may be more flexibly applied in cases where the expert testimony is based on experience.” *In re Front Loading Washing Mach. Class Action Litig.*, 2013 WL 3466821, at \*2 (D.N.J. July 10, 2013). Moreover, in the case of experience-based opinions, the fact that an expert has been determined to be qualified weighs in favor of the reliability of her report. *Altieri v. State Farm Fire & Cas. Co.*, 2011 WL 1883054, at \*3 (E.D. Pa.

May 17, 2011). In this Circuit, “courts limit the *Daubert* inquiry to expert testimony offered to prove satisfaction of Rule 23’s requirements.” *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 188 n.8 (3d Cir. 2015).

### **C. Relevance**

The third requirement of Rule 702, known as relevance or fit, is satisfied “if an opinion fits a particular case (and thus helps the trier of fact)” – i.e., there must be a “connection between the scientific research or test result to be presented and particular disputed factual issues in the case.” *Geiss*, 2013 WL 4675377, at \*5 (internal quotation marks omitted).

## **III. BACKGROUND ON DR. CONTI’S EXPERT REPORT**

### **A. Dr. Conti’s Qualifications**

Defendants diminish Dr. Conti’s vast expertise by merely describing her as an “associate professor” and an affiliate of a “consulting and litigation support firm.” In reality, Dr. Conti received her Ph.D. in Health Policy (Economics Track) from Harvard University. Conti. Decl. at ¶ 17. She previously served as an Instructor at the University of Chicago, Department of Pediatrics, where her principal research interests focused on the economics of the medical care industry. *Id.* at ¶ 12. She currently serves as Associate Professor of Markets, Public Policy and Law in the Questrom School of Business at Boston University, where she teaches courses on the economics of the medical care industry, and her research

interests focus on the economics of the healthcare industry and the markets for pharmaceutical drugs in particular. *Id.* at ¶¶ 12-14.

In addition to being a Professor of Healthcare Economics and serving as a consultant through Greylock McKinnon Associates, Dr. Conti has also published 100 research publications in peer-reviewed health economics and policy journals. Conti Decl. at ¶ 15. These peer-reviewed publications have focused on topics including examinations of insurer-related reimbursement and coverage issues, trends in pharmaceuticals use, and pricing of pharmaceuticals. *Id.* Dr. Conti has testified before the Senate Finance Committee on causes of ongoing pharmaceutical shortages. *Id.*

Dr. Conti also has testified at FDA hearings on issues related to pharmaceutical quality. *Id.* She has given invited talks to the United States Government Accountability Office (“GAO”), the Congressional Budgetary Office (“CBO”), the Federal Trade Commission (“FTC”), the National Institutes of Health (“NIH”), and the FDA, among other governmental agencies. *Id.* Moreover, Dr. Conti has served as a consultant to the FDA’s Office of Generic Drugs on issues related to drug quality and adequacy of supply. *Id.* Dr. Conti has also served as a member National Academy of Sciences, Engineering and Medicine’s Committee on Ensuring Patient Access to Affordable Drug Therapies. *Id.* She is also serving as an *ad hoc* advisor to the National Academy of Sciences,

Engineering and Medicine's Committee on Security of America's Medical Product Supply Chain. *Id.*

Additionally, Dr. Conti has submitted expert testimony in complex matters involving health economics and allegations related to pharmaceutical sales, pharmaceutical quality, pricing, insurance, and reimbursement and regulation. *Id.* at ¶ 16. Among these matters is *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, in which she opined (as she opines here) that adulterated drugs are economically worthless. The *BCBS* court found Dr. Conti's opinions there to be reliable and admissible. 2019 WL 4751883 (E.D. Pa. Sept. 30, 2019).

#### **B. Dr. Conti's Opinions and Methodology**

Dr. Conti principally opines on the economic value of the at-issue VCDs in this case, and how to calculate the class-wide damages suffered by putative class members for their purchases of these products.

*First*, Dr. Conti accepted for her analysis Plaintiffs' allegations that Defendants' VCDs were adulterated or misbranded. Specifically, she assumes – quite properly and permissibly – that Defendants' VCDs were contaminated with nitrosamines and/or were manufactured so out of compliance with cGMPs that the

drugs were adulterated and/or misbranded the entire time they were being sold on the market.<sup>1</sup>

To arrive at an economic value for the at-issue VCDs, Dr. Conti applies her vast experience and research regarding the generic drug regulatory landscape, and the associated pricing issues, to identify the pertinent factors that would go into making such a valuation. Dr. Conti opines that when economic loss Class Members purchased generic prescription drugs (in this case, the at-issue VCDs), they did so with the expectation that the drugs are what they are represented to be, are not contaminated with any harmful substances, and have been produced in accordance with cGMPs. Conti Decl. ¶¶ 4-7, 31-38. The cGMPs and applicable standards, as Dr. Conti opines, are meant to assure that the drugs meet the legal requirements for safety and have the quality, purity, identity, and strength they are represented to possess. *Id.*

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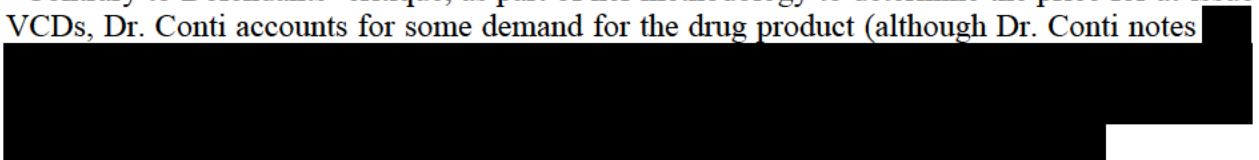
<sup>1</sup> Defendants make much hay over the fact that Plaintiffs' Counsel asked Dr. Conti to assume liability – that the drugs were manufactured in violation of cGMPs (the *prima facie* evidence of this being FDA determinations regarding same, as well as the contamination with NDMA/NDEA). Mfr./Retailer Br. at 2. It is permissible for a damages expert to assume liability in proposing a damages model. *U.S. Accu-Measurements, LLC v. Ruby Tuesday, Inc.*, 2013 WL 1792463, at \*8 (D.N.J. Apr. 26, 2013) (“Expert opinions on damages commonly assume liability[.]”). The question of whether the Defendants' manufacturing practices were so wholly non-compliant will be for the fact-finder, not an expert. To have required Dr. Conti to independently conclude such facts would usurp the province of the jury. Dr. Conti's opinion on the value of the VCDs only comes into play if the factfinder makes a determination that the drugs were manufactured in this non-compliant manner and/or were otherwise adulterated or misbranded.

Dr. Conti describes that these assurances to consumers and TPPs are the “foundation upon which prescription drugs are sold and purchased in the United States. *Id.* ¶ 21. This is because, as Dr. Conti explained in her deposition, for a prescription drug to be permitted to enter the United States class of trade, manufacturers must attest that they are manufacturing the drug in a cGMP compliant manner. *See* Ex. A, Conti Dep. Tr. Vol. I at 116:15-118:4. Similarly, Defendants’ own experts have conceded that for a generic drug to be considered “therapeutically equivalent” for purposes of Orange Book substitutability, the generic drug must have been manufactured in compliance with cGMPs. D.E. 2036.

Dr. Conti explains that as a matter of economic theory, for there to be a price associated with a particular drug product, there needs to be both demand and a supply. Ex. A, Conti Dep. Tr. Vol. I. at 182:6-183:7. As these products should not have been allowed to be sold in the U.S. supply chain, there is no legitimate supply curve for them because federal law (and analogous state laws) prohibit the sale of adulterated drugs.<sup>2</sup> Indeed, Dr. Conti further explained that while a hypothetical consumer may want (or demand) an illegal or illegitimate product, such products still have no economic value because a pharmacy is not permitted to sell products

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<sup>2</sup> Contrary to Defendants’ critique, as part of her methodology to determine the price for at-issue VCDs, Dr. Conti accounts for some demand for the drug product (although Dr. Conti notes



which do not meet the necessary regulatory requirements that they be manufactured in a safe and effective manner. *Id.* at 124:7-15. Other undisputed record evidence supports this. For instance, as noted in Plaintiffs’ class certification reply brief, every Retail Pharmacy and Wholesaler Defendant’s corporate designee testified [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Next, Dr. Conti goes about determining the supply for the at-issue VCDs. As part of this task, Dr. Conti reviewed and analyzed the larger context of the FDA regulatory landscape. Ex. A, Conti Dep. Tr. Vol. I at 124:7-15. Dr. Conti is certain that understanding the regulatory and legal realities of pharmaceutical drug sales is a key component of assessing the supply of the at-issue VCDs. *Id.* This is because the prescription drug market is one of the most “highly regulated consumer product markets” that exists. *Id.* at 124:16-25.

As Dr. Conti testified, for drugs to be able to be sold in this highly regulated market, pharmaceutical manufacturers must meet the baseline standard of “quality manufacturing” in addition to providing a drug that is both safe and efficacious. *Id.* at 125:1-6. The participants in this market, the drug manufacturers themselves, “know[] what the rules are.” *Id.* To the extent these VCDs did not meet this

standard, as Plaintiffs intend to demonstrate at trial, Dr. Conti has concluded there can be no legitimate supply. *Id.*

Dr. Conti concludes there is no equilibrium between the demand for safety and quality compliant drugs and the supply of non-compliant drugs. *Id.* Stated another way, there can be no meeting of demand and supply to arrive at a “price” for the drugs. *Id.* at 126:19-127:3. Dr. Conti describes this as “Economics 101.” *Id.* at 188:14-25. Had the true nature of the drug products and the manner in which they were manufactured been known, these products would not have met the baseline standards to be allowed into the U.S. market, which would result in them not being viewed as legitimate products. *Id.* at 156:18-24.

Under these circumstances, and in light of the economic realities of the supply and demand curves for these particular products, Dr. Conti concludes that these drugs are economically worthless. *Id.* Again, as noted in Plaintiffs’ class certification reply brief, Defendants’ own economic loss experts acknowledge that, if there is no legitimate supply, then all consumers (even a hypothetical consumer who might have wanted to buy a contaminated or adulterated VCD, which of course is a false construct because Defendants themselves say they would not knowingly sell such products), would end up “paying no money for [Defendants’ VCDs]” and that there would be “no intersection of supply and demand” exactly in

the way Dr. Conti describes and models it in her report. *See* D.E. 2057 at 15 & nn.30-32.

**Second**, after assigning Defendants' VCDs a \$0 value based on their economic worthlessness, Dr. Conti then proceeds to calculate aggregate damages attributable to the various classes. Conti Decl. ¶¶ 55-79. With the exception of Wholesaler Defendants' Unjust Enrichment damages (for sound economic reasons and defense-created data limitations, discussed *infra*), Dr. Conti calculates these aggregate damages as the total cost paid, by either the consumer or TPP class member. Because Dr. Conti concluded that the value of Manufacturer Defendants' VCDs was \$0, the class members would be entitled to the full purchase price of their drug (i.e., what they paid at point of sale).

Dr. Conti calculates the aggregate damages for the Manufacturer classes using IQVIA<sup>3</sup> Xponent Data. *Id.* ¶¶ 55, 71. For the Retail Pharmacy Consumer Classes,<sup>4</sup> Dr. Conti relied on the Retail Pharmacy Defendants' own data to conduct her calculations. *Id.* ¶ 78. Using that data, Dr. Conti overlaid the VCDs' NDC Codes and then summed the total paid by drug, pharmacy, and state. *Id.* ¶¶ 78-79.

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<sup>3</sup> The Xponent data captures both retail and mail order pharmacy claims and includes the full cost (which is a combined amount paid by both the consumer and the TPP), as well as the consumer payment. *Id.* Using these data sets, Dr. Conti calculated the damages to the Consumer and TPP Classes, by specific state. *Id.* ¶¶ 72-77, 79.

<sup>4</sup> TPP Classes do not seek certification of any claims against Retail Pharmacy Defendants.

Dr. Conti necessarily uses a slightly different approach to calculate unjust enrichment damages for Wholesaler Defendants because they did not manufacture the at-issue VCDs like the Manufacturer Defendants, nor did they directly sell product to class members like the Retail Pharmacy Defendants. *Id.* ¶ 80.<sup>5</sup>

Dr. Conti's damages calculations also stratify class-wide damages by Defendant (e.g., by each Manufacturer, Retail Pharmacy, or Wholesaler), by theory of liability (e.g., manufacturers' breach of express warranty, and so forth), and by state. *Id.* ¶¶ 58-59 & Attachments C-I. She also presents "deduplicated" damages in the event that the factfinder finds certain defendants liable under multiple theories (e.g., breach of implied warranty and unjust enrichment). *Id.* ¶ 79. Thus, Dr. Conti's model is flexible enough to account for however the Court may certify and prioritize certain claims, against certain defendants, under certain states' laws, or for certain findings by a jury (e.g., if the time period at issue is shorter or longer than that alleged). *Id.* ¶ 11.

#### **IV. ARGUMENT**

##### **A. Another Court in This Circuit Has Already Found Dr. Conti Qualified and Her Opinions Reliable in a Case Nearly Identical to This One**

Defendants relegate (to a footnote) the highly pertinent fact that another court in this circuit has already analyzed Dr. Conti's qualifications and

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<sup>5</sup> This is discussed more fully in response to Wholesaler Defendants' flawed critique *infra*.

methodology (nearly identical to that she employs here); found her to be qualified; found her methodology reliable; and, therefore, found her opinions admissible. *Blue Cross Blue Shield Ass’n v. GlaxoSmithKline LLC*, 2019 WL 4751883, at \*8–9 (E.D. Pa. Sept. 30, 2019) (“*BCBS*”).

In *BCBS*, thirty-eight different TPPs sought to recoup their reimbursements for drugs that were adulterated due to cGMP failures. *Id.* at \*1. The *BCBS* plaintiffs, as Class Plaintiffs argue here, argued that the adulterated drugs were economically worthless and they would not (and could not) have been purchased had the manufacturer disclosed the cGMP deficiencies and adulteration. *Id.*

In support of their claims, the *BCBS* plaintiffs relied on Dr. Conti’s economic analysis that “there can be no legitimate supply curve to establish economic value” for drugs made in a non-cGMP compliant manner “because the FDCA prohibits the sale of adulterated drugs.” *Id.* at \*2.

The *BCBS* defendants sought to exclude Dr. Conti’s opinions for many of the same reasons Defendants argue here. For instance, the *BCBS* defendants argued that Dr. Conti impermissibly based her opinion on a legal interpretation, that her model was not based on reliable economic methodology, and that her calculations were flawed for not assessing other data points such potential offsets or rebates. *Id.* at \*8. Judge Sánchez thoughtfully analyzed and rejected each challenge, *see id.* at \*7-8, and ultimately found that the defendant’s critiques went

to credibility, not admissibility, *id.* at \*8.

Rather than acknowledge the *BCBS* ruling, Defendants impugn Judge Sánchez by accusing him of having “abdicated” his judicial obligations and not conducting a “serious analysis.” D.E. 2040-1 at 8. Defendants’ inappropriate *ad hominem* attacks against a federal jurist who issued an unfavorable ruling should be disregarded<sup>6</sup> out of hand, and this Court rightfully be guided in its own analysis by that which preceded it in *BCBS*.

**B. Dr. Conti is Qualified to Opine on Issues Related to Wholesaler Defendants**

Only Wholesalers, in their standalone brief, argue that Dr. Conti is unqualified to offer her opinions, specifically those related to Wholesaler Defendants’ Unjust Enrichment damages. D.E. 2037 (hereafter “Wholesaler Br.”). Wholesaler Defendants claim she lacks “specialized expertise” to offer her damages opinions because she never worked for a wholesaler or signed a drug purchase or sales agreement on behalf of one. Wholesaler Br. at 5. Wholesalers’ contention that a healthcare economist such as Dr. Conti cannot opine on unjust enrichment damages using a well-established, court-accepted methodology

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<sup>6</sup> It is preposterous to imply the Honorable Juan Sánchez “abdicated” his judicial duties. Plaintiffs will note that the Defendant in the *BCBS* case (GlaxoSmithKline, a multi-national and sophisticated pharmaceutical manufacturer with high-powered attorneys from New York) did not seek to reconsider or appeal the *Daubert* ruling, which one might expect them to do if they themselves believed the Judge had acted in such a recklessly negligent manner.

because she was never an insider who worked at a wholesaler is borderline laughable. The Wholesalers' argument is even more contrived given the posture of this briefing, at the class certification stage, when the exact contours of the claims and defenses remain in flux prior to certification and summary judgment.

“[T]he qualification standard is a liberal one.” *Holbrook v. Lykes Bros. S.S. Co., Inc.*, 80 F.3d 777, 782 (3d Cir. 1996). An expert may be qualified if she has “a broad range of knowledge, skills[,]” including informal qualifications such as real-world experience. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994). Moreover, a Court may not exclude an expert “simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate.” *Holbrook*, 80 F.3d at 782.

Against this legal backdrop, it is clear Wholesalers' qualifications-related critique must fail. For one, there is no serious dispute that Dr. Conti is eminently qualified, through her robust training and experience, to opine on economic damages suffered by the proposed classes. Wholesalers do not dispute this. Rather, they vaguely assert that their wholesaler business is so niche or specialized that any damages expert needs “specialized expertise” to proffer opinions, such as “experience with Wholesaler contracts and data,” or “work in the wholesaler industry.” Wholesaler Br. at 3. As case in point, not a single one of Defendants'

experts worked for a Wholesaler Defendant. Many did not review *any* materials from Wholesalers, be it documents or testimony.<sup>7</sup> Yet Wholesalers affirmatively rely on these experts' opinions, obviously finding these experts qualified enough to have rendered opinions about their companies' business practices.

No legal requirement exists, and Wholesalers certainly cite none, that a *damages* expert must have directly worked for a particular type of defendant to opine on damages calculations, or that the wholesaler drug industry is so incredibly unique that calculating profits (based on their own sales data) is simply beyond the reach of anyone but a former wholesaler insider. Examples of this are legion.<sup>8</sup> This is because “[t]he question of whether an expert properly performed calculations or interpreted their results ordinarily goes to the weight of the evidence, not to its admissibility.” *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 83 (3d Cir. 2017). This is especially true where, as here, the legal rubric for calculating damages is well-established *legal* principle that transcends industries: unjust enrichment damages are a defendant's ill-gotten gains (profits), and a defendant may attempt to offset by showing costs. *See infra* Part IV.E..

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<sup>7</sup> See, e.g., D.E. 2046-1, Stiroh Rpt. Ex. 2 (showing Dr. Stiroh reviewed no wholesaler data or 30(b)(6) testimony), D.E. 2048-1, Keller Rpt. App. B (same for Ms. Keller), D.E. 2041-1, Kosty Rpt. App. C (same for Mr. Kosty).

<sup>8</sup> See, e.g., *In re Mushroom Direct Purchaser Antitrust Litig.*, 2015 WL 5767415, at \*3-5 (E.D. Pa. July 29, 2015) (finding an expert with no specialized mushroom experience qualified); *Voilas v. Gen. Motors Corp.*, 73 F. Supp. 2d 452, 457 (D.N.J. 1999) (finding an expert with no specialized automotive experience qualified); *Nielsen Audio, Inc. v. Clem*, 2017 WL 1483353, at \*2 (M.D. Fla. Apr. 24, 2017) (finding an expert with no specialized radio sales experience qualified).

Wholesalers also are incorrect that Dr. Conti has zero familiarity with the drug supply chain, including the wholesale level. Wholesaler Br. at 5-6. Dr. Conti has consequential experience with the entire drug supply chain from a health economist standpoint. Conti Decl. App. A (demonstrating that she has served as special advisors to several presidential candidates on the issue of the prescription drug market and provided governmental testimony on the generic drug supply). As Dr. Conti explained, she has been on panels, at conferences, and in closed-door meetings discussing specific issues related to reimbursement, financing, organization and regulation of the wholesaler industry. Ex. B, Conti Dep. Tr. Vol. II at 102:1-21. Further, Dr. Conti has personally worked with former executives at Cardinal and AmerisourceBergen (two of the three Wholesaler Defendants here) on issues related to pharmaceutical drug supply issues. *Id.* at 103:19-25. Were this not enough (and it should be), Dr. Conti teaches about wholesalers' role in the pharmaceutical drug supply chain at Boston University. *Id.* at 101:17-21.

Further, Dr. Conti has reviewed the type of data Wholesalers maintain in the ordinary course of business in the context of her larger work, although in deposition, because of the confidentiality agreements associated with that work, she was not permitted to fully discuss her experience with it. *Id.* at 106:4-6. To the extent Wholesalers nitpick that she did not review heavily redacted agreements that do not reveal any pricing terms, or dig deeper into Wholesalers' purported

costs on a micro-granular level, those arguments (which are Wholesalers' burden to make anyways) go to weight, not admissibility, and are discussed more fully *infra* Part IV.E.

In short, as Dr. Conti explained, she has spent “every day for the past 20 years thinking about” how drugs go through the supply chain, which includes wholesalers (and, ultimately, pharmacies). *Id.* at 106:15-107:5. She has more than enough specialized experience to opine on issues related to Wholesalers.<sup>9</sup> Even if, *arguendo*, there may be other experts more qualified to testify about Wholesalers' activities, Dr. Conti very clearly has the minimum baseline specialized expertise necessary to opine on damages modeling in this litigation. To the extent Dr. Conti has not checked every box in Wholesalers' self-serving and arbitrary criteria, any purported gap in her qualifications is immaterial because that goes to the weight of her testimony, not its admissibility. *See, e.g., Pineda*, 520 F.3d at 244 (“it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate”); *Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 809-10 (3d Cir. 1997) (reversing exclusion of expert for purported gap in qualifications).

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<sup>9</sup> Wholesaler Defendants did not seek out their own expert with more specialized experience to rebut the testimony of Dr. Conti, and instead appear to rely on their own witnesses self-serving affidavits offered up as part of the discovery dispute discussed more fully at IV.E as part of their *Daubert* arguments.

### **C. Dr. Conti's Opinions Are Reliable**

Defendants' purported reliability-related arguments range from disagreeing with Dr. Conti's conclusion that the at-issue VCDs are economically worthless (Mfr/Retailer Br. at 8-10), to arguing she ignores "therapeutic value" (*id.* at 10-11), to contending their own counter-factual hypothetical scenario in which consumers would and could still buy contaminated or adulterated VCDs (*id.*) to claiming they are entitled to offsets (*id.* at 16-18). None of these present a legitimate basis to challenge the reliability and application of Dr. Conti's methodology.

Plaintiffs respond to each of Defendants' misguided attacks below. But an overarching consideration is that the standard for reliability is lower than the merits standard for determining whether the expert is correct. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 155-56 (3d Cir. 2000). So long as an expert's testimony rests upon good grounds, based on what is known, "it should be tested by the adversary process -- competing expert testimony and active cross-examination -- rather than excluded from jurors' scrutiny." *Id.*

This is especially true in cases involving experts in the field of economics. Because the discipline of economics requires "the use of professional judgment" the expert testimony of an economist is less likely to be excluded because challenges may ultimately be viewed as matters where "reasonable experts may differ." *In re Mushroom Direct Purchaser Antitrust Litig.*, 2015 WL 5767415, at

\*6 (E.D. Pa. July 29, 2015); *see, e.g., United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004).

**i. Defendants Incorrectly Focus on Dr. Conti's Conclusions,  
Not Her Methodology**

Simply put, Defendants disagree with Dr. Conti's conclusion that at-issue VCDs were economically worthless. *See, e.g., Mfr/Retailer Br.* at 9 (criticizing "Dr. Conti's conclusion of worthlessness"). They relatedly challenge Dr. Conti's assumption that at-issue VCDs were adulterated, and claim her conclusion is flawed because it is "contrary to common sense." *Id.* at 3.

Mere disagreement with an expert's conclusions, rather than her methodology, is not an appropriate basis for challenge under *Daubert*. The Court's *Daubert* analysis must be driven by the methodology and expertise employed, and not the ultimate conclusions upon which the expert arrives. *Jama v. Esmor Corr. Servs., Inc.*, 2007 WL 1847385, at \*27 (D.N.J. June 25, 2007) ("The Supreme Court in *Daubert* has stated that the focus of the inquiry should be solely on principles and methodology, not on the conclusions that they generate." (citing *Daubert*, 509 U.S. at 596)); *see, e.g., Lambeth Magneti Structures, LLC v. Seagate Tech. (US) Holdings, Inc.*, No. 16-438, 2022 WL 864170, at \*1 (W.D. Pa. Mar. 22, 2022) ("disagreement with [expert's formulation] does not render her opinion inadmissible under *Daubert*. Rather, such arguments properly go to the weight of the evidence.").

As discussed *supra* Part III.B, Dr. Conti properly applied a reliable methodology to the facts of this case. Her opinions align with the theories of liability in this case. Defendants' disdain with her conclusions does not implicate the reliability, and thus the admissibility, of her opinions.

To the extent Defendants argue Dr. Conti's damages models are unreliable because she was asked to assume "that the [VCDs] at issue in this litigation had zero value," Mfr/Retailer Br. at 1, that is simply incorrect. Dr. Conti was not asked to assume the drugs had zero value. Rather, Dr. Conti was asked to assume the question of liability (i.e., that the drugs were contaminated, adulterated and misbranded). Ex. A, Conti Dep. Vol. I Tr. at 169:33-170:2; *see also* Conti Decl. ¶ 2. Upon making this assumption, Dr. Conti then proceeded to apply her economic expertise to determine the appropriate price an economic loss plaintiff should have paid for the drugs from 2012-2018. When Dr. Conti's methodology, discussed *supra* at Part II.B, is applied to the facts of this case, she concludes that the products were worth \$0. Conti Decl. ¶ 7. There is nothing improper, let alone unreliable, with such an assumption. These are exactly the types of assumptions that *damages* experts routinely must and do make. *See, e.g., Rhoads Indus., Inc. v. Shoreline Found., Inc.*, 2021 WL 2778562, at \*30 (E.D. Pa. July 2, 2021) ("In fact, all damages expert opinions are dependent . . . on the assumption that liability has been proven.") (internal quotation marks and citation omitted).

**ii. Dr. Conti Incorporates Therapeutic Value in Her Analysis**

Defendants also argue that Dr. Conti's methodology is unreliable because she "ignored" the question of the therapeutic value the product may have provided to a given class member. However, Dr. Conti does not ignore therapeutic value. As Dr. Conti testified, the question of economic value and therapeutic value are two different concepts. Ex. A, Conti Dep. Tr. Vol. I at 183:11-21. Dr. Conti accounts for the therapeutic value of the product to the individual consumer in the demand curve. *Id.* In a situation where there is a legitimate supply of product, Dr. Conti testified that consumers often trade off the benefits and costs of product. *Id.* However, in this situation presented here, because there is no supply curve for illegitimate, adulterated and misbranded product in her model (and, as Downstream Defendants testified, in the real world), there is no price, and thus the at-issue VCDs are economically worthless. *Id.*

Again, this aligns with the facts in this case, and concessions from Defendants' own experts. As discussed above, Downstream Defendants cannot and do not knowingly sell adulterated drugs. *See supra* Part III.B. This Court has previously recognized the economic harm class members suffered occurred at the point of sale, which is what Dr. Conti calculates. *See, e.g.,* D.E. 775 at 19-20 ("... contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were

never bargained for.”).<sup>10</sup>

Given such, as Defendants’ own experts concede, the potential “therapeutic value” of adulterated or misbranded VCDS is irrelevant to economic damages analysis if the appropriate measure of damages is the benefit of the bargain. *See* D.E. 2057 at 15 & nn.30-32. And ultimately, as the *BCBS* court held, whether “Plaintiffs’ damages calculation [by Dr. Conti] is improper because Plaintiffs should have discounted any therapeutic value they received from the noncompliant drugs [] is necessarily a credibility dispute between the parties’ experts.” *BCBS*, 417 F. Supp. 3d at 557.

### **iii. Dr. Conti’s Methodology Incorporates the Real World of Prescription Pharmaceutical Sales**

Related to Defendants’ contention about “therapeutic value” is their equally specious contention that Dr. Conti failed to account for a mythological creature of Defendants’ own flawed machinations: a hypothetical consumer in a counterfactual, but-for world who wanted to *and* did continue to purchase at-issue VCDs *after* the truth was disclosed about the NDMA/NDEA contamination and cGMP

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<sup>10</sup> Defendants’ feigned indignation (Mfr./Retailer Br. at 4) over plaintiffs’ counsel’s texting Dr. Conti during a deposition break is a red-herring. This was a remote deposition due to COVID; Dr. Conti reviewed a publicly available document during a break; and Dr. Conti testified that she had looked at the publicly available document during the break when the deposition resumed. As Defendants acknowledge, Plaintiffs produced the text (which was the exact public document Dr. Conti referenced, and which Counsel had to text to her because and could not be handed to her as would have happen with an in person deposition). Plaintiffs willingly made such a production of this text notwithstanding the fact that Defendants have never produced documentation of their communications with *their own* witnesses during breaks.

failures. *See* Mfr/Retailer Br. at 10-12. Defendants’ straw-man invention does not impugn the reliability of Dr. Conti’s methodology and analysis.

First, unlike Defendants and some of their experts, Dr. Conti’s methodology incorporates and relies upon actual, real-world pharmaceutical sales data and other facts. Specifically, Dr. Conti (a frequent collaborator and speaker on issues related to generic drug approval, unlike Defendants’ experts, Dr. Stiroh or Ms. Keller) acknowledges the complex regulatory forces at play during every sale of a prescription drug product in the United States, *see* Conti Decl. ¶¶ 21-38, and that the FDA “does not allow drugs to be sold in the U.S. market that do not meet” the baseline standards for compliance with cGMP, safety, and efficacy. Ex. A, Conti Dep. Vol. I Tr. at 125:23-126:11. Downstream Defendants’ own admissions confirm this. *See supra* Part III.B. Further still, Dr. Conti’s analysis of actual, real-world data confirms the obvious: [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Thus, it matters not that some hypothetical consumer might have wanted to buy adulterated VCDs, as Defendants claim. They could not do so, and the real-world data confirmed they did not. Likewise, Defendants do not cite any proposed class representative’s testimony that they actively sought out contaminated, adulterated, or misbranded

VCDs following the recalls, versus a non-adulterated alternative.

Finally, whether Dr. Conti should have put all of the real-world facts and data aside (and indulge Defendants' own hypothetical construct of some made-up consumers who still wanted to and did buy adulterated VCDs contaminated with a known carcinogen), is a disputed fact upon which different parties may disagree. An expert is permitted to base their opinion on a particular version of disputed facts, and the weight to be accorded to that opinion is for the jury. *Walker v. Gordon*, 46 F. App'x 691, 696 (3d Cir. 2002).

**iv. Defendants' Arguments About Point-of-Sale Offsets Are Irrelevant to Reliability**

Defendants obliquely suggest Dr. Conti's methodology is unreliable because it does not exhaustively account for potential offsets, rebates, refunds or other after-the-fact adjustments. *See, e.g.*, Mfr./Retailer Br. at 18. This attack fails for at least three reasons.

*First*, Defendants' argument here is tentative at best; they stop short of stating, let alone arguing, that any class member actually received a refund or credit. *See id.* ("Like TPPs, consumers *may* receive post-sale refunds or credits") (emphasis added). Notably, they do not cite any of their own data suggesting any refunds or credits – because they never produced any such data.

Even if such data existed, Dr. Conti's model is flexible enough to accommodate for them if the factfinder so decides. Her model was devised to

“accommodate factual or legal findings the jury or the Court makes” such as offsets. Conti Decl. ¶ 11. Dr. Conti demonstrated a willingness to incorporate this data, provided that Defendants actually produced the data they claim she ignored (which they have not). Ex. B, Conti Dep. Tr. Vol. II at 165:23-166:2 (“A: So, again, my -- my damage calculation is flexible and could accommodate the possibility of refunds that were made for recalled or contaminated product to end-payors. I did not have that data for this analysis that I conducted.”).

**Second**, as thoroughly set forth in Plaintiffs’ reply in further support of their motion for class certification, the question of potential offsets, rebates, or other items neither precludes class certification nor renders an expert’s damages calculations unreliable. *See, e.g., W. Palm Police Pension Fund v. DFC Global Corp.*, 2016 WL 4138613, at \*14 (E.D. Pa. Aug. 4, 2016) (citing *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 374 (3d Cir. 2015); *Gen. Employees’ Retirement Sys. v. Prudential Fin., Inc.*, 2015 WL 5097883, at \*13 (D.N.J. Aug. 3, 2015) (“[T]he need to perform individual damages calculations does not foreclose class certification under Rule 23(b)(3).”). This is because such adjustments go to the extent, not the fact, of injury. Indeed, the Third Circuit has indicated that denying class certification based on a finding of individualized damages would “amount[] to an abuse of discretion.” *Neale*, 794 F.3d at 375; *see also In re Novo Nordisk Sec. Litig.*, 2020 WL 502176, at \*9 (D.N.J. Jan. 31, 2020).

**Third**, and relatedly, the question of potential offsets or rebates is itself a common one. To hold otherwise would incentivize bad-actor defendants, which courts have repeatedly refused to do.<sup>11</sup>

**Finally**, “courts do not require damages to be reduced to a mathematical certainty,” especially at this class certification stage. *In re Suboxone Antitrust Litig.*, 421 F. Supp. 3d 12, 40 (E.D. Pa. 2019); *see also, e.g., Page v. State Farm Life Ins. Co.*, -- F. Supp. 3d -- (W.D. Tex. Feb. 10, 2022) (recommending denial of *Daubert* challenge and certification of class; discussing how post-verdict class damages can be adjusted if jury finds any offset appropriate).

#### **D. Dr. Conti’s Opinions Fit the Liability in this Case**

Defendants appear to raise two relevance or “fit” arguments (although they do not address them as such): (i) Dr. Conti’s full purchase price damages model should be excluded because it seeks the full refund of the product (Mfr/Retailer Br. at 12-15), and (ii) Wholesalers’ professed belief that unjust enrichment damages are so easy to understand there is no need for Dr. Conti’s opinions (Wholesaler Br.

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<sup>11</sup> *See Korolshteyn v. Costco Wholesale Corp.*, 2017 WL 1020391, at \*8 (S.D. Cal. Mar. 16, 2017) (“allowing class members to obtain a refund is not an alternative to ‘adjudicating’ whether Defendants are liable for material misrepresentations on the labels of their products....[otherwise defendants] could freely misrepresent the benefits of their products secure in the knowledge that their return policy effectively immunizes them from any suit seeking restitution.”); *Allen v. Holiday Universal*, 249 F.R.D. 166, 194-95 (E.D. Pa. 2008) (granting class certification and finding that “[t]here are questions of law and fact common to the Class, namely: . . . If liability is proven, whether continued usage of the club and/or continued payment under contract off-sets any respective class member’s right to collect any monetary damages.”); *see also Andrako v. U.S. Steel Corp.*, 788 F. Supp. 2d 372, 382 (W.D. Pa. 2011) (“individualized damages defenses should not preclude collective adjudication of the critical issue[s] in this case”).

at 7-12). Both arguments lack merit.

“Fit” is a relatively low bar. It simply means the expert’s testimony must assist the trier of fact (i.e., be helpful), and be related to the theories of liability in the case (i.e., relevant). *See, e.g., Comcast Corp. v. Behrend*, 569 U.S. 27, 37-38 (2013); *United States v. Ford*, 481 F.3d 215, 219-20 (3d Cir. 2007) (finding that the threshold for analyzing fit is “not high.”). Here, Dr. Conti’s opinions fit in terms of helpfulness and relevance.

**First**, Plaintiffs’ theories of liability turn on whether the at-issue VCDs were economically worthless at the point of sale. Dr. Conti’s opinions track these theories perfectly. She unpacks complex pharmaceutical industry supply chain dynamics and economic theory to demonstrate, using real-world data, on a defendant-by-defendant, state-by-state, and theory-by-theory basis, how damages should be calculated. *See supra* Part II.B. Unquestionably, her opinions fit the facts and theories in this case, and will help a lay jury understand all of the complexities underlying damages to the classes.

What Defendants really appear to dispute is whether point-of-sale (or purchase-price or full-refund) damages models are appropriate to measure damages in cases where plaintiffs allege a product is worthless (both in situations where the product was contaminated, and also in situations where the product was otherwise safe but was not what it purported to be (e.g., made in a cGMP compliant manner)).

Plaintiffs addressed this in their Reply Brief in Support of Class Certification, setting forth how courts routinely find damages models like Dr. Conti's sufficiently reliable, including but not limited to *BCBS*.<sup>12</sup> That Defendants believe another measure of damages may be more appropriate does not render Dr. Conti's well-applied model unreliable or inadmissible.<sup>13</sup> *See, e.g., In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Prac., & Prods. Liab. Litig.*, 509 F. Supp. 3d 116, 192 (D.N.J. 2020) (factfinder to decide between experts' competing testimony and methodologies).

**Second**, Wholesalers' contention that Dr. Conti's unjust enrichment calculations are not helpful to a lay jury because her opinions rely on a "commonly known and widely available" formula (Wholesaler Br. at 7), strains credulity. On

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<sup>12</sup> *See, e.g., Steroid Hormone Prod. Cases*, 181 Cal. App. 4th 145, 150-159 (2010) (approving full refund damages model where supplements were contaminated with illegal steroid, and as a result of such contamination the products would be illegal to purchase and sell: "in this case Martinez does not put valuation at issue when he alleges that he bought a product that was illegal to sell or possess."); *In re Amla Litig.*, 282 F. Supp. 3d 751, 756, 767 (S.D.N.Y. 2017); *Krueger v. Wyeth, Inc.*, 2011 WL 8971449, at \*2 (S.D. Cal. Mar. 30, 2011); *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 524 (6th Cir. 2015).

<sup>13</sup> Defendants' cited cases are readily distinguishable. With respect to *Shahinian* (initially filed by disgraced and disbarred former attorney Michael Avenatti), the case involved the sale of medical gowns, not maintenance therapy hypertensive drugs contaminated with carcinogens. *Shahinian v. Kimberly-Clark Corp.*, No. CV 14-8390-DMG (PLAx), 2017 U.S. Dist. LEXIS 233811, at \*33 (C.D. Cal. Mar. 7, 2017). There, the Court recognized while it did not believe the surgical gowns were worthless, there may be other adulterated products with no legitimate market where a different court could arrive at a different outcome. *Id.* at \*33 (C.D. Cal. Mar. 7, 2017) (conceding that adulterated milk contaminated with water and salt may be worthless because there is no market for it). The product at issue in the Center City Periodontists case is likely distinguishable (allegedly ill-fitting dental equipment). *Rezulin* and *Baycol* are likewise distinguishable. Both cases involved overlapping claims for personal injury and product liability type claims.

the one hand, Wholesalers argue their industry and pricing is so impenetrably complex that no one, Dr. Conti or otherwise, can begin to understand their ill-gotten gains (and potential costs, which is Wholesalers' burden to prove, *see infra* Part IV.E). Yet at the same time they argue unjust enrichment is so easy to calculate a lay juror can do it herself (armed with an economics textbook and internet connection, *see* Wholesaler Br.at 8), for thousands of class members strewn across more than two dozen states, over a several-year period. Wholesalers cannot have it both ways. For present purposes, it suffices that Dr. Conti presents a reliable method for estimating unjust enrichment damages that is flexible enough to account for whatever costs a factfinder ultimately may find should offset Wholesalers' revenues. *See, e.g., KCH Servs. v. Vanair, Inc.*, 2010 WL 1416672, at \*2 (W.D. Ky. Mar. 31, 2010) (finding that even in situations where the calculations are simple addition and subtractions, an expert, such as a healthcare economist, is necessary to help a jury know which fields to add or subtract). As to Dr. Conti's inability to fully apply her model at this time because Downstream Defendants have not yet produced their cost data, *see infra* Part III.E.

#### **E. RETAILER AND WHOLESALER UNJUST ENRICHMENT DAMAGES**

Both sets of Downstream Defendants (Retail Pharmacies and Wholesalers) critique Dr. Conti's methodology for calculating Unjust Enrichment damages. While these Defendants' particular critiques differ, their root grievance is the same:

they fault Dr. Conti for not fully calculating their own respective costs, and then reducing their revenues (i.e., the ill-gotten gains) by those costs to arrive at net profits. *See, e.g.*, Mfr/Retailer Br. at 18-26; Wholesaler Br. at 14. This overarching critique fails, and certainly does not affect the admissibility of Dr. Conti's opinions, because Downstream Defendants *did not produce their cost data*. Plaintiffs vigorously sought cost data but were denied it. The Downstream Defendants cannot withhold information in discovery and then fault Plaintiffs and their expert for not using that same data.

Retail Pharmacies' related criticism, that Dr. Conti's approach to calculating Retail Pharmacy Unjust Enrichment Damages varies slightly, from her approach to Wholesalers' Unjust Enrichment Damages, misses the mark. These two tiers of defendants are differently situated in the supply chain and different data points (e.g., retail point-of-sale data) exist for the different entities.

**i. Plaintiffs' Expert Cannot Be Faulted For Not Considering Data Wholesaler and Retail Pharmacy Defendants Refused to Provide**

Distilled to its essence, Dr. Conti reliably opines that Downstream Defendants' ill-gotten gains from the at-issue VCDs they sold is presentable as revenue minus costs. Conti Decl. ¶¶ 64-66, 82-85. Downstream Defendants agree. *See, e.g.*, Mfr/Retailer Br. at 24 ("profits are defined as revenue minus costs"); *id.* at 25 ("Disgorgement is measured in terms of 'net profits'"). Wholesalers go so

far as to claim this formula is so unassailable that no expert testimony is even needed because a juror can go on the career advice page of indeed.com to calculate the damages. *See supra* Part IV.D, Wholesaler Br. at 8. Thus, there is no dispute that Dr. Conti reliably identifies an appropriate measure of unjust enrichment type damages.

Downstream Defendants fault Dr. Conti, however, for her purported failure to actually deduct their own costs from their revenues to arrive at net profits. For one, at this stage, Plaintiffs need not calculate damages to a “mathematical certainty.” *In re Suboxone*, 421 F. Supp. 3d at 40. This is especially true where, as here, the precise states’ laws at issue have yet to be decided via class certification; summary judgment has yet to crystallize the claims and issues; and the defendants have yet to file answers to the master complaints (or to assert affirmative defenses). Any perceived failing in this regard implicates the suitability of unjust enrichment classes for certification, and not the overall admissibility of Dr. Conti’s opinions.

More significantly, Plaintiffs *explicitly sought* Downstream Defendants’ cost data years ago, but were denied it. The parties engaged in extensive briefing over the scope of Plaintiffs’ discovery requests to Wholesaler and Retail Pharmacy Defendants, which included requests for cost data and information—i.e., the very data Downstream Defendants now fault Plaintiffs for not using in Plaintiffs’ estimates of class-wide unjust enrichment damages.

By way of background, in 2019, Magistrate Judge Schneider initially prioritized discovery on Manufacturer Defendants and focused the parties' efforts there. Only after Judge Schneider had ruled on several "macro-discovery" issues pertaining to Manufacturer Defendants, which resulted in his entering 122 court-approved document requests to Manufacturer Defendants did the Court turn to Downstream Defendants. *See* D.E. 328.

Plaintiffs began the process of seeking discovery from Wholesaler and Retail Pharmacy Defendants in December 2019 by serving initial documents requests that mirrored the Court-approved requests to Manufacturer Defendants. Plaintiffs' draft written discovery included several requests for cost information. *See, e.g.*, D.E. 323-1 (Retail Pharmacies); D.E. 323-2 (Wholesalers).

At Magistrate Judge Schneider's urging, in the ensuing months, Plaintiffs worked diligently to sharply limit their requests to Downstream Defendants. *See* D.E. 413 & Exs. B-C thereto. The parties reached agreement on all requests *except* two which are incredibly pertinent here: requests seeking (i) data showing how much consumers and TPPs paid for VCDs, and (ii) cost data so Retail Pharmacy and Wholesaler Defendants' "ill-gotten profits can be calculated for damages purposes." D.E. 413 at 4, 7-8. In their briefing, Plaintiffs explicitly stated they seek cost data to calculate "unjust enrichment or disgorgement of ill-gotten gains." *Id.* at 8.

Downstream Defendants vigorously opposed producing cost data, *see* D.E. 479 (Retail Pharmacies); D.E. 478 (Wholesalers), on a variety of grounds, including that the unjust enrichment count might be dismissed because at the time defendants had yet to file motions to dismiss, that cost data was “confidential,” and that production might entail some burden that these defendants should not have to incur if these claims were dismissed from the litigation at the Rule 12(b)(6) stage. D.E. 478; D.E. 479. Plaintiffs replied, noting that the issue had been narrowed to the production<sup>14</sup> of “cost data.” D.E. 501 at 4.

Magistrate Judge Schneider heard oral argument on July 6, 2020.<sup>15</sup> The next day, he issued an order “denying without prejudice” Plaintiffs’ request for cost data and TPP sales data<sup>16</sup> from Downstream Defendants. D.E. 507. He then issued Court-approved requests to these defendants that did not include requests for cost data. D.E. 509.

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<sup>14</sup> As Plaintiffs predicted in their letter, “to calculate disgorgement damages, Plaintiffs need to establish Retail Pharmacy [and Wholesaler Defendants’] profits on their sales of finished-dose valsartan.” D.E. 501 at 4. Plaintiffs also explicitly noted that “cost offsets will be *Defendants’* burden at trial, not Plaintiffs’ burden.” *Id.*

<sup>15</sup> During this hearing, Counsel for McKesson assured Magistrate Judge Schneider that should he rule in their favor (and deny the request for cost data), it would not have any “implications” that could “inhibit” a class argument based on disgorgement of profits. *See* Ex. E, 7/6/2020 Hr’g Tr. at 72:19-73:16. Retail Pharmacies’ liaison counsel could not even fathom how non-production of cost data could impact class certification. *Id.* at 74:19-74:2.

<sup>16</sup> It goes without saying that the entire cost discussion as it relates to the Retail Pharmacy Defendants cannot be untethered from their refusal to produce TPP sales data for the VCDs. The Retail Pharmacy Defendants argued that only the consumer payment was relevant. The Court agreed with them “without prejudice.” Now, Retail Pharmacy Defendants argue that Plaintiffs’ damages are unreliable for failing to include accurate cost data to deduct from their co-pays. But, of course, this cost data cannot be assessed without knowing the full amount a Retail Pharmacy Defendant received for a drug, not just the consumer portion.

Two things are clear from this lengthy recitation of the record. First, Wholesalers are dead wrong that Plaintiffs never sought cost data. *See* Wholesaler Br. at 3 n.2. Plaintiffs did, multiple times, specifically articulating that cost data was needed to calculate ill-gotten gains (revenue less costs).

Second, and more saliently for this *Daubert* briefing, Downstream Defendants cannot withhold from discovery information sought by Plaintiffs, only then to fault Plaintiffs (and Plaintiffs' experts) for not having the very data Defendants went to great lengths to hold back. *See, e.g., Ware v. Riley*, 587 Fed. App'x 705, 711-12 (3d Cir. Oct. 8, 2014) (affirming district court order preventing party from arguing at trial evidence that party failed to produce during discovery); *see also* Fed. R. Civ. P. 37(c)(1). Indeed, it is Defendants' burden to demonstrate that certain costs should be deducted from the reasonable estimate of profits. *See Softel, Inc. v. Dragon Med. & Sci. Commc'ns Ltd.*, 891 F. Supp. 935, 939 n.3 (S.D.N.Y. 1995) ("defendants have the burden of showing the costs that should be taken into account in assessing damages"), *order aff'd and remanded sub nom.*, 118 F.3d 955 (2d Cir. 1997).

To see how Courts have dealt with this issue in the class certification context, the Court can look to *In re Blood Reagents Antitrust Litigation* for guidance. 2015 WL 6123211 (E.D. Pa. Oct. 19, 2015). There, the defendant withheld cost data from production and then opposed class certification and the plaintiffs' economic

expert for not using “reliable cost data.” *Id.* at \*17-18 & n.15 (“The Court is concerned about defendant’s use of its failure to produce reliable cost data as both a sword and shield in this case.”). Ultimately, the *Blood Reagents* court did not exclude the plaintiffs’ expert, finding the matter of what costs should have been accounted for is “more a question of the accuracy of [his] analysis,” not necessarily the methodology he used in conducting [his] analysis.” *Id.* at \*18 (internal quotations marks omitted). The “alleged flaws,” the court found about the costs that should or should not be included in the model, “are appropriate fodder for cross examination at trial.” *Id.*; *see also, e.g., In re Actiq Sales & Mktg. Pracs. Litig.*, 2014 WL 3572932, at \*9 (E.D. Pa. July 21, 2014) (rejecting defense contention that expert’s damages model should be excluded for failing to include certain categories of costs that defendant asserted led to an inaccurate representation of profitability).

Wholesalers’ assertion that they do not accurately keep their own product-level cost data (*see* Wholesaler Br. at 9-13) should be disregarded as irrelevant to the *Daubert* analysis, and a disputed *common* fact question.<sup>17</sup> Regardless,

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<sup>17</sup> For example, Wholesaler Defendants cite to a slew of declarations (previously appended to letter briefs related to discovery disputes) as a form of contradictory pseudo-expert support arguing Dr. Conti’s methodology is unreliable. Wholesaler Br. at 13. As a threshold matter, Wholesaler Defendants cannot now use these declarations as some sort of pseudo-expert support when Plaintiffs were not even permitted to ask the affiants any questions about how those declarations were drafted and what material they relied on to draft them. *See, e.g.,* Ex. D, Brett Harrop (McKesson 30(b)6)) Dep. Tr.at 28:12-30:2. But more than that (and continuing with Mr.

Plaintiffs need not calculate damages to a “mathematical certainty,”<sup>18</sup> a wrongdoer defendant cannot benefit from its own poor records,<sup>19</sup> a jury need only a reasonable basis to award damages.<sup>20</sup> Indeed, were Wholesaler Defendants correct that a defendant can avoid unjust enrichment damages or disgorgement entirely simply by neglecting to keep disaggregated product cost data (something that remains an open question because Plaintiffs did not have full discovery of Downstream Defendants’ costs, how they estimate costs when purchasing drugs, etc.), then no defendant would ever be liable for any damages under any unjust enrichment or similar theory. This is not the law of any jurisdiction, and Wholesalers certainly cite no case for their outlandish proposition.

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Harrop as an example), when probed about the statements in his declaration related specifically unjust enrichment damages, Mr. Harrop actually testified that [REDACTED]

<sup>18</sup> *In re Suboxone*, 421 F. Supp. 3d at 40.

<sup>19</sup> The Supreme Court “has sustained recovery of the full amount of defendant’s profits where his own wrongful action has made it impossible for the plaintiff to show in what proportions he and the defendant have contributed to the profits.” *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 265 (1946). The argument does not defeat class certification. More significantly, any such cost-based argument is itself a common question amenable to class-wide proof. *See Wynn Oil Co. v. Am. Way Serv. Corp.*, 943 F.2d 595, 607 (6th Cir. 1991) (plaintiff’s efforts to ascertain defendant’s profits were frustrated by defendant’s insistence that its profits could not be readily determined; court held that “common sense” dictated that the burden of apportioning profits be placed on defendant); *S & K Sales Co. v. Nike, Inc.*, 816 F.2d 843, 852 (2d Cir. 1987) (citing cases).

<sup>20</sup> *See, e.g., Leonard v. Stemtech Int’l Inc.*, 834 F.3d 376, 390 (3d Cir. 2016) (uncertainty on precise amount of damages does not preclude jury award); *Sigma Photo News, Inc. v. High Soc’y Magazine, Inc.*, 778 F.2d 89, 95 (2d Cir.1985) (“Confronted with imprecision in the computation of expenses, the court should err on the side of guaranteeing the plaintiff a full recovery.”).

**ii. Retail Pharmacy and Wholesaler Defendants Unjustly  
Benefitted in Different Ways**

Retail Pharmacy and Wholesaler Defendants ignore that Dr. Conti made calculation adjustments because of the downstream defendants' posture in the overall distribution of the products to the Economic Loss Consumer Plaintiffs. Indeed, with respect to all damages, as Dr. Conti testified, "retailers sold their product to consumers, and they obtained their own benefit from the consumers" which is necessarily different than the benefit received by the wholesalers. Ex. B, Conti Dep. Tr. Vol. II 48:15-21. This is likewise true for Unjust Enrichment Damages. *Id.* at 48:3-10. Also, Dr. Conti did consider the possibility of other potential offsets or costs associated with each transaction that had not been otherwise included. Conti Dep. Tr. Vol. II at 60:18-61:25. These further deductions could be accounted for if and when Downstream Defendants produce the necessary data.

**V. Conclusion**

For the foregoing reasons, the Manufacturer & Retail Pharmacy Defendants' and Wholesaler Defendants' Motions to Exclude should be denied.

Dated: June 2, 2022

Respectfully submitted,

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### **CERTIFICATE OF SERVICE**

I hereby certify that on this 2nd day of June, 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ David J. Stanoch

David J. Stanoch